Alta Bates

MEDICAL CENTER

IN VITRO FERTILIZATION PROGRAM

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5360 Fishers Lane Room 1061
Rockville, MD 20852

RE: Docket #97N-484S, Suitability Determination for Donors of Human Cellular and Tissue-Based Products

Dear Sir: December 17, 1999

With regards to the proposed requirement for cryo-preservation of human embryos with retesting of the donor after 6 months before the embryos are replaced into the infertile recipient, I believe that this requirement would significantly lower the success rate of treatment without significantly enhancing its safety.

The fragility of eggs and embryos by comparison with sperm make this proposal biologically and medically questionable. The safety track record of many years of donor egg treatments in the United States renders this onerous requirement unnecessary. Currently available technology for screening and testing of donors provide sufficient margin of safety.

In the absence of adverse events with the current procedures, infertile consumers are entitled to accept the minimal risk of transmission of an infectious agent in order to benefit from the high pregnancy rate achievable with this "last ditch" treatment option.

Sincerely,

Ryszard J. Chetkowski, M.D.

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